PT-DDS4 Media Preparation and Degassing System

Media degasing or “de-aeration”, pre-heating to a temperature of 37℃ and absolutely precise gravimetric dispensing according to the recommendations and demanded for dissolution testing from the US FDA authorities are standard for the Pharma Test **PT-DDS4** media preparation and degasing system. De-aeration is generally recommended to prevent the formation of bubbles on the dosage form surface, which may cause a variation in active dissolution rates, by virtue of surface obscuration.

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Effective media de-aeration is one of the most important requirements for a successful tablet dissolution test. USP reference standard tablets (RST) for PVT tests in particular, react very sensitive to ineffectively de-aerated media. Often the test fails to arrive at the required results for the release, even if all technical parameters of the dissolution bath in use have been checked and passed the tests.

A save and efficient way of media de-aeration of un-dissolved oxygen (O^2) is offered by the techniques the PT-DDS4 is using. The prepared media (buffer) is filled by means of vacuum or manually into the storage and heating tank of the instrument. While the media is heated, it is being constantly circulated under vacuum within the tank. Because of this way of operating, the PT-DDS4 provides fully de-aerated and preheated media ready to be dispensed into the USP dissolution vessels. Therefore another huge advantage of media preparation in this way is the time saved during the startup of subsequent dissolution runs, because the media is already at the required testing temperature of 37℃. PT-DDS4 is more effective than other available instruments, because the de-aeration process can be maintained for as long as required, as opposed to instruments which only de-aerate during the actual dispensing.

PT-DDS4 features a large back-lit LCD screen. The user menu offers the possibility to program the dispensing (weight) volume, the temperature to pre-heat the media and the total de-aeration time. All information including dosed weight/volume and statistics can be printed via the built-in thermo printer.

The portable nature PT-DDS4 instrument offers the user easy servicing of many dissolution baths. The built-in pre-heating tank is easily removable for cleaning. Open the drainage valve and empty the tank of any medium left. Flush the tank again and repeat the software assisted process. When the media has to be changed, a tube flushing run is automatically done previous to any dispensing.

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Factors affecting the PQ results:

Type	Rating	Influence degree
Temperature	**not too significant**	linear
Speed	**significant**	10-30%
Vibration	**reasonable**	5-10%
Centricity	**reasonable**	± 5-15%
Dissolved Gas	**significant**	± 50%
Media pH	**reasonable**	± 5-10%
Media Contamination	**significant**	± 20-45%
Sampling Position	**not too significant**	1-3%

The influence of air inside the media on Tablet Dissolution Test results

Non-de-aerated media have a definite impact on the results of a tablet dissolution test. For example, non-de-aerated media can increase Prednisone release rate up to 50% compared to the release rate using properly de-aerated media.

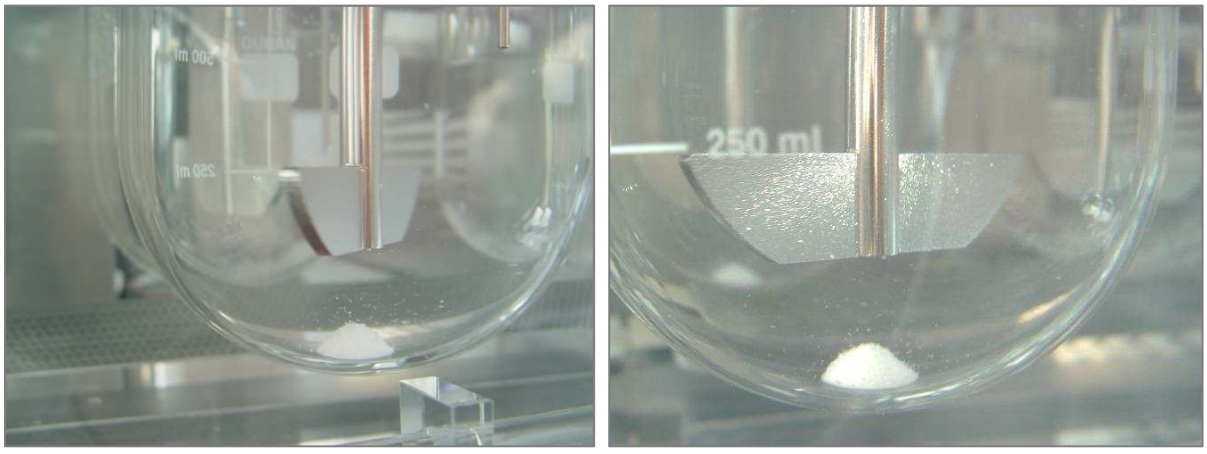

Figure 1: Prednisone Test after 10 Min, using De-Aerated Media - No Floating Particles

Figure 2: Prednisone Test after 10 Min. using Non-De-Aerated Media - Increased Release Rate because of floating particles, lower tablet cone

Handling of Foaming Media with PT-DDS4

To improve the degassing and dosing of foaming media, like SPS with the Pharma Test PT-DDS4 media preparation system, a new alternative inlet tube system is available now.

A curved inlet tube can be used as an alternative to the standard diffuser inlet. The curved inlet tube directs the medium against the barrel wall, where it can gently flow down the tank, thus preventing an excessive foam build-up. The inlet tubes can be changed freely by the user. The inlets are secured by a knurled head screw. An upgrade kit for existing PT-DDS4 instruments is available as well.

Gravimetric Dosing is the Most Accurate Method of Liquid Dispensing!

In this mode, the medium is directly dispensed into the dissolution vessel, which is placed safely in its stand during filling. The dosing volume can be adjusted within a range of 250 to 5,000g with an accuracy of ±0.5%, max. ±1ml. This accuracy is much better than what any current Pharmacopoeia requires. Enter the media density to correct the dosing. The temperature can be adjusted as well, within a range of 30.0℃ to 50.0℃ with an accuracy of ± 0.5℃.

The media is constantly circulating while the vacuum level is kept constant.

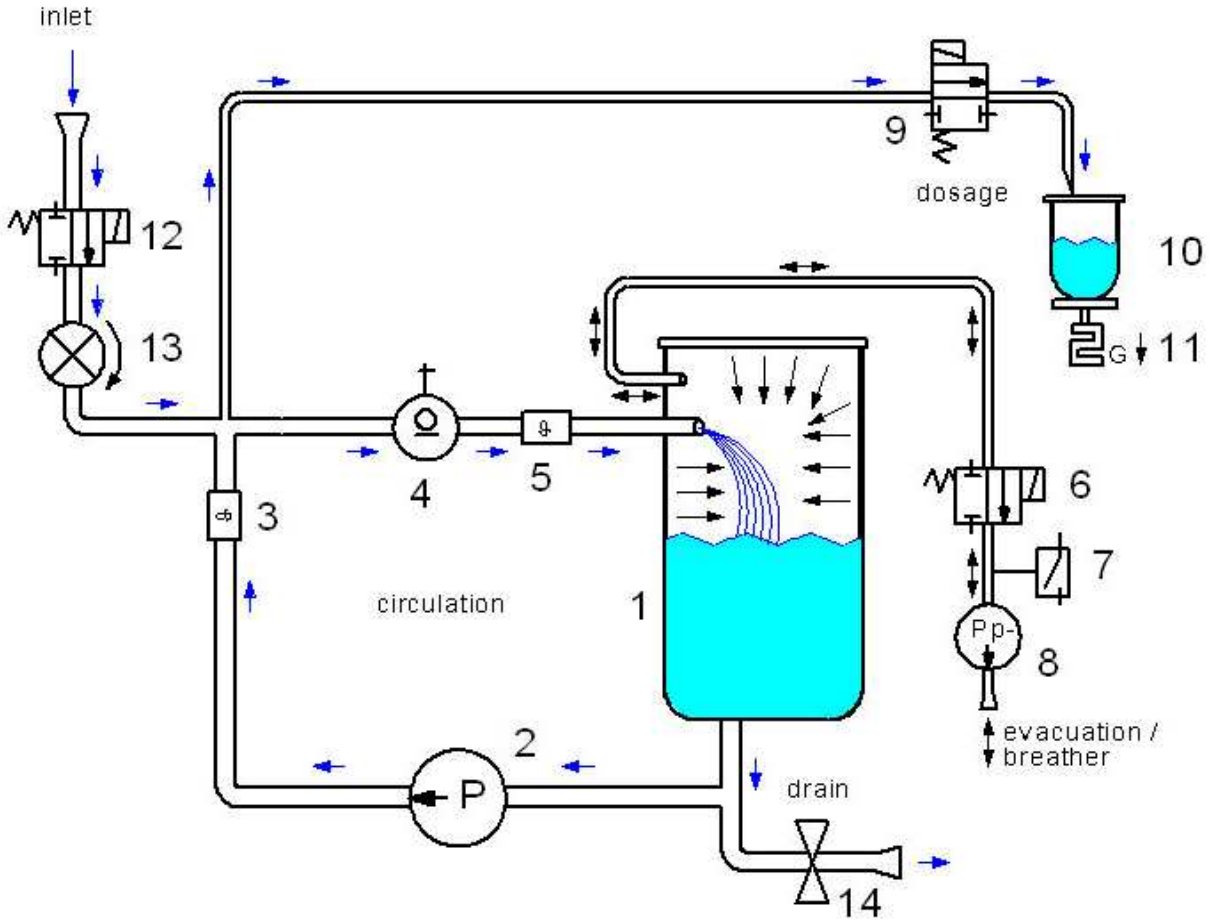

Figure 3: Operating Principle Gravimetric Dosage

Legend:

1: Medium Reservoir	2: Circulation Pump	3: Temp. Control Sensor
4: Heater	5: Temp. Security Sensor	6: Decompression Valve
7: Vacuum Switch	8: Vacuum Pump	9: Dosage Valve
10: USP Vessel	11: Load Cell	12: Inlet Valve
13: Inlet Flow Sensor	14: Drain Valve	

Volumetric Dosage is Selectable As Well

This mode of dosage is very convenient and time effective for the end user. Here, the de-aerated medium is filled directly into the dissolution vessels which are installed in the dissolution bath. The design of the filling arm ensures a slow filling along the side of the vessels to avoid oxygen saturation while filling.

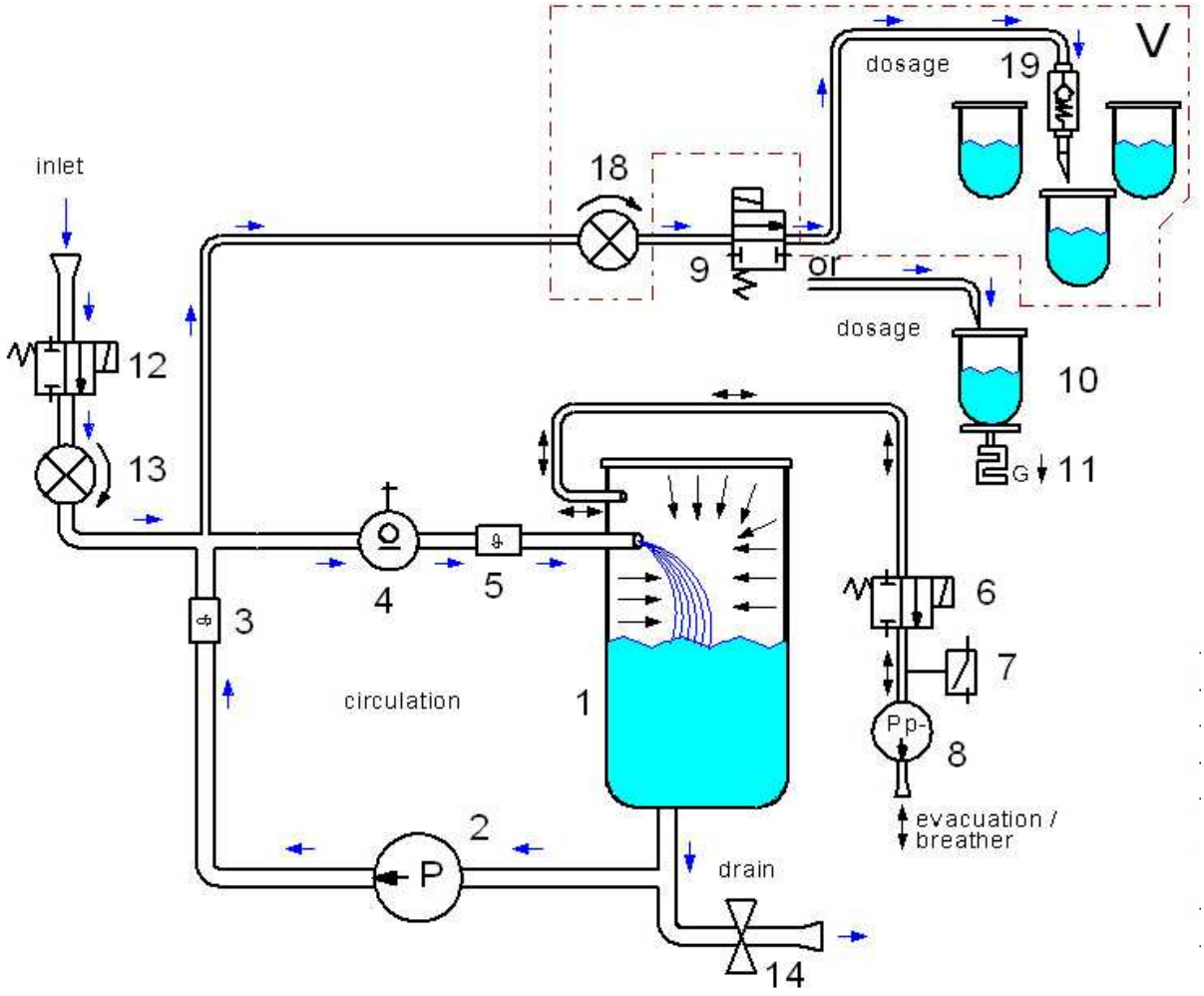

Figure 4: Operating Principle Volumetric Dosage

Legend:

1: Medium Reservoir	2: Circulation Pump	3: Temp. Control Sensor
4: Heater	5: Temp. Security Sensor	6: Decompression Valve
7: Vacuum Switch	8: Vacuum Pump	9: Dosage Valve
10: USP Vessel	11: Load Cell	12: Inlet Valve
13: Inlet Flow Sensor	14: Drain Valve	18: Dosage Low-Flow Sensor
19: Dosage Check Valve		

Online Buffer Mixing Using the Built-in Electronic Load Cell (Balance) is Available as Well

Simply enter the amount and density of the buffer (range from 100g to 5,000g) to be filled into the pre-filled storage tank.

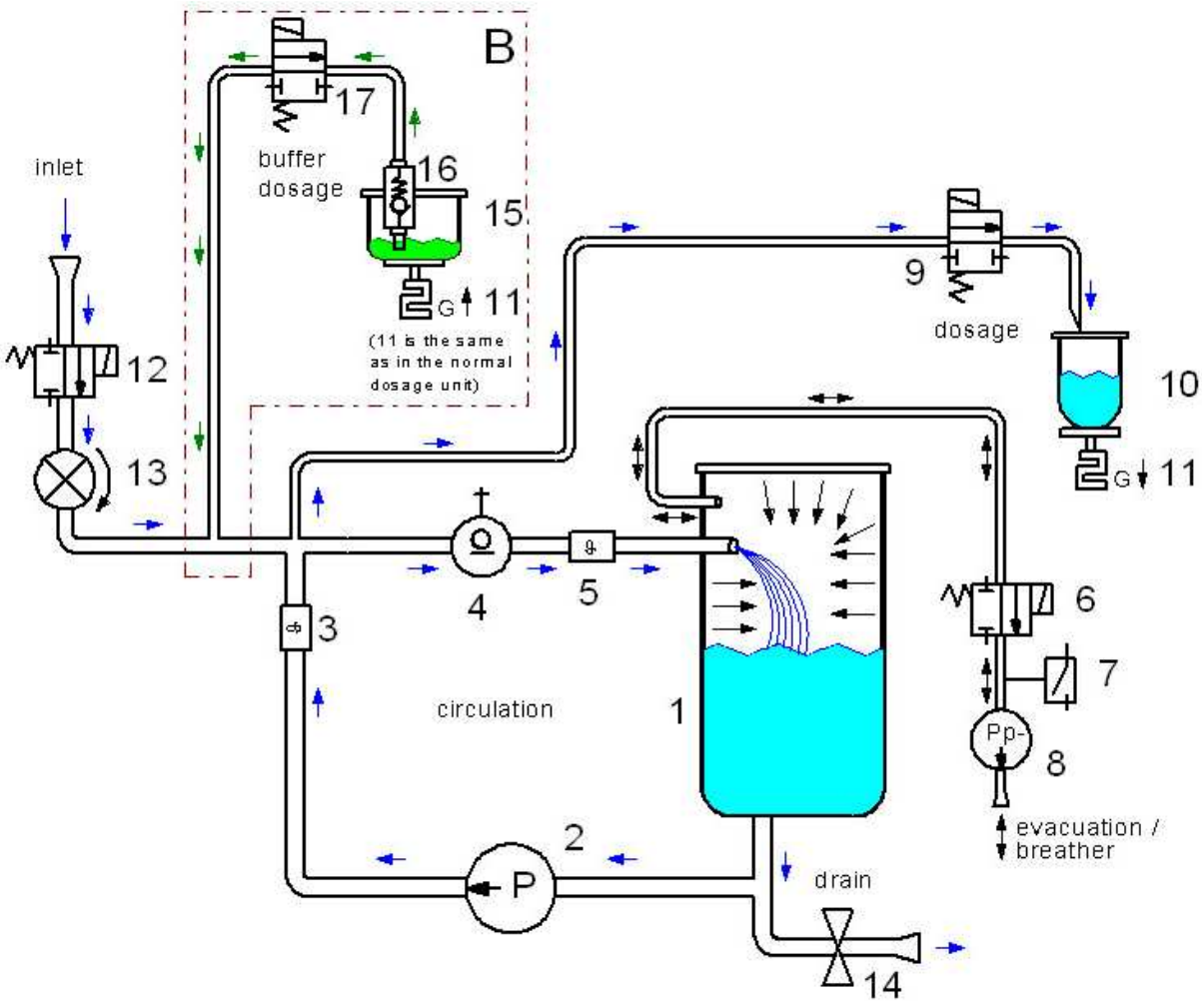

Figure 5: Operation Principle Buffer Preparation Station

Legend:

1: Medium Reservoir	2: Circulation Pump	3: Temp. Control Sensor
4: Heater	5: Temp. Security Sensor	6: Decompression Valve
7: Vacuum Switch	8: Vacuum Pump	9: Dosage Valve
10: USP Vessel	11: Load Cell	12: Inlet Valve
13: Inlet Flow Sensor	14: Drain Valve	15: Buffer Beaker
16: Check Valve	17: Buffer Dosage Valve	

Figure 6: Directly Filling a Vessel using the Volumetric Dosing Option

Advantages

Some of the highlights the PT-DDS4 offers are:

- De-aerates to approx. 35% of rest gas content (residual oxygen less than 5 ppm inside PT-DDS4 container)
- Pre-heats your media to save time during start-up of dissolution tests
- Fill-up program under pressure (connect directly to factory de-min. water supply)
- Fill-up program under vacuum (prime from any external container)
- Can be upgraded to de-aerate and dispense SPS foaming media
- Can be used to directly dose into any vessel arrangement inside the dissolution bath
- Special adapter to handle foaming media available (optional)
- The instrument is movable and fits underneath most laboratory benches
- Includes a balance (load cell) and all accessories for gravimetrical dosing
- Good access to the media tank, easy to control the cleaning and test procedure
- The only instrument which offers a software supported calibration program to validate and calibrate dosing accuracy using a certified 1 kg weight
- Dosing performance test possible using built-in strain gauge
- Correct dosing accuracy by entering density of media (changes because of temperature or solvent used)
- Maximum of 2 liters waste when media change has to be done
- Noise protected, max. noise level approx. 55dB
- IQ/OQ documents included free of charge

Features

The main features of the PT-DDS4 are:

- De-aeration and heating of approx. 24 liters of media at the same time
- Pre-heating of media; target temperature adjustable from 30 – 50℃
- Adjustable gravimetric dosing range: 250 – 5,000g
- Adjustable volumetric dosing range: 250 – 5,000ml (optional)
- Online buffer mixing, adjustable buffer dosing range: 100 – 5,000g (optional)
- LC display and keypad to show and enter data, like product information, batch no., media density, etc.
- Live information about the remaining tank volume; minimum 1 liter
- File up to 16 de-aeration procedures (methods)
- Built-in adjustment and calibration program for the digital load cell and flow-meter
- Built-in thermo printer to report the dosed media weight or volume and to document of adjustment and calibration results

Standard Scope of Supply

The PT-DDS4 comes ready to use with the following standard scope of supply:

- Gravimetrical dosing set-up
- Electro polished stainless steel tank - max. capacity approx. 24 liters
- Stainless Steel dosing dish to hold dissolution vessels
- Comprehensive documentation folder including:
  - User manual
  - DQ/QC instrument compliance test certificate
  - IQ documentation
  - OQ documentation
  - Instrument logbook

Options

In addition to the standard scope of supply Pharma Test offers a broad range of accessories and options including:

- Volumetric dosing system
- pH buffer dosing system
- Upgrade kit for foaming media
- Support stand to take up to 6 USP vessels
- Full range of certified validation tools including DO^2 tester to read the amount of de-aeration available

Technical Data

Parameter	Specification
Dosing Range	250 – 5,000g - gravimetric method 250 – 5,000ml - volumetric method
Dosing Accuracy	±0.5% of selected volume - gravimetric method ±0.8% of selected volume - volumetric method
Tank Volume	Approx. 24 liters
Dispensing Time for 1 Liter	Approx. 45 - 60 seconds
De-aeration and Heating Time	24 liters within approx. 30 - 45 minutes
Display	LC Display 320x240 pixels, 8 x 8cm screen
Data Entry	Alpha numerical keypad
Method Memory	Store up to 16 methods
Printer	Thermo printer, 24 characters
Interface	RS232 port
Vacuum Level	0.4 bar absolute
Temperature Range	30.0 – 50.0℃
Temperature Accuracy	±0.5℃
Heater Capacity	900W
Calibration	Built-in calibration procedures for digital load cell (weight), digital flow meter (volume) temperature control
Space Requirements	55 x 70 x 90cm (W/D/H)
Height of Dispenser	130cm from ground floor
Net Weight	Approx. 75 kg
Gross Weight	Approx. 110 kg
Packaging Dimensions	107 x 97 x 78cm (W/D/H)
Certification	All components certified to USP / EP requirements
CE / EMC Certification	All CE / EMC Certification provided
Validation	All IQ & OQ documents included

We reserve the right to make technical changes without any prior notice.

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